



APR 17 2002

Mr. David Kropp
Director, Regulatory and Consumer Affairs
Pharmavite Corporation
PO Box 9606
Mission Hills, California 91346

Dear Mr. Kropp:

This is in response to your letter of March 20, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Pharmavite Corporation is making the following claim, among others, for the product **Folic Acid**:

"A deficiency of folic acid during pregnancy has been linked to several birth defects, such as the neural tube defect spina bifida. Therefore, it is critical for women of child-bearing age to consume 400 mcg of folic acid per day."

These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but are health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim for folate and neural tube defects on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.79 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, neural tube defects.

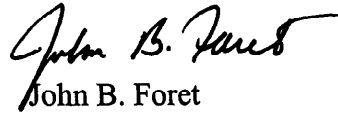
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Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

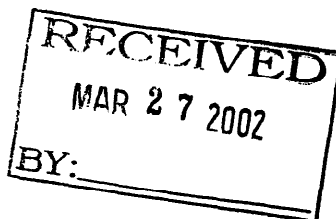
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



March 20, 2002



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Folic acid, also known as folate and folacin, is essential in cell division, DNA synthesis, and the manufacturing of brain chemicals, or neurotransmitters in the body. Without adequate levels of folic acid, cells do not divide properly. Folic acid is vital to the development of the nervous system of a fetus.. A deficiency of folic acid during pregnancy has been linked to several birth defects, such as the neural tube defect spina bifida. Therefore, it is critical for women of child-bearing age to consume 400 mcg of folic acid per day. In addition, folic acid may also play a significant role in heart health. It does so by helping to keep homocysteine levels down in the blood. Homocysteine is a substance that formed when Vitamin B12 and folic acid levels are low, and research has indicated it may be a possible factor for heart health.
- (3) Name of the dietary ingredient if not provided in the text of the statement:
Folic Acid
- (4) Name of the dietary supplement:
Folic Acid

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Optimize, Spring Valley, Walgreens.

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PHARMAVITE

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

David Krepp
Director, Regulatory and Consumer Affairs

